

## Department of Commerce

1352.235-70

address: [Insert Contracting Officer name and Address]

(c) Agency protests filed with the agency Protest Decision Authority shall be sent to the following address: [Insert appropriate Protest Decision Authority name and Address]

(d) A complete copy of all agency protests, including all attachments, shall be served upon the Contract Law Division of the Office of the General Counsel within one day of filing a protest with either the Contracting Officer or the Protest Decision Authority.

(e) Service upon the Contract Law Division shall be made as follows: U.S. Department of Commerce, Office of the General Counsel, Chief, Contract Law Division, Room 5893, Herbert C. Hoover Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230. FAX: (202) 482-5858.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

### 1352.233-71 GAO and Court of Federal Claims protests.

As prescribed in 48 CFR 1333.104-70(a), insert the following provision:

#### GAO AND COURT OF FEDERAL CLAIMS PROTESTS (APR 2010)

(a) A protest may be filed with either the Government Accountability Office (GAO) or the Court of Federal Claims unless an agency protest has been filed.

(b) A complete copy of all GAO or Court of Federal Claims protests, including all attachments, shall be served upon (i) the Contracting Officer, and (ii) the Contract Law Division of the Office of the General Counsel, within one day of filing a protest with either GAO or the Court of Federal Claims.

(c) Service upon the Contract Law Division shall be made as follows: U.S. Department of Commerce, Office of the General Counsel, Chief, Contract Law Division, Room 5893, Herbert C. Hoover Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230. FAX: (202) 482-5858.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

### 1352.235-70 Protection of human subjects.

As prescribed in 48 CFR 1335.006(a), insert the following provision:

#### PROTECTION OF HUMAN SUBJECTS (APR 2010)

(a) Research involving human subjects is not permitted under this award unless ex-

pressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(b) The Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR part 27, requires contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a "human subject" as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR part 27. These categories may be found at 15 CFR 27.101(b).

(c) In the event the human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR part 46 subpart B, C and D, as appropriate, for the protection of members of a protected class.

(d) Should research involving human subjects be included in the proposal, prior to issuance of an award, the contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board ("cognizant IRB"). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB possesses a valid registration with the United States Department of Health and Human Services' Office for Human Research Protections ("OHRP");

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by OHRP.

(e) Prior to starting any research involving human subjects, the contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate